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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/034,950	12/26/2001	Bhami Shenoy	VPI/00-08	9344

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EXAMINER	
FETTEROLF, BRANDON J	
ART UNIT	**PAPER NUMBER**
1642	

DATE MAILED: 06/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/034,950	SHENOY ET AL.	
	Examiner	Art Unit	
	Brandon J Fetterolf, PhD	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-78* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-78* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Upon review and reconsideration, the previous restriction requirement mailed 5/19/2004 is hereby vacated.

Claims 1-78 are pending.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

The Embodiments of I-VI described below consists of various groups and should not be construed as groups but Embodiments:

I. Claims 4-11, 13, 15-39, 43-68, 70-71, and 74-76, as specifically drawn to a crystal of an antibody, a composition or formulation containing a crystal of the antibody, a large batch crystallization method and a diagnostic kit, classified in class 530, subclass 387.3; class 424, subclass 178.1.

(**Applicant must choose ONE specific crystal of an antibody as a group, as each crystal of an antibody is a distinct invention, NOT a species. Applicant is also required to list ALL claims which would read on the elected crystal of an antibody**)

An appropriate group selection of Embodiment I would be for example, Rituximab (claim 13) is the specific antibody characterized as being monoclonal (claim 6), chimeric (claim 8), used as a therapeutic agent (claim 5) for treating cancer (claim 16), which can be placed within the anti-CD20 antibodies (claim 15).

(The applicant is not limited to the claims provided in the example described above and is required to list ALL claims which would read on the elected crystal of an antibody)

II. Claims 12, 16-18, 24-30, 43-68, 70-71, and 74-75 as specifically drawn to a crystal of an anti-idiotypic antibody, classified in class 530, subclass 387.2.
(**Applicant must choose ONE specific crystal of an anti-idotypic antibody as a group, as each crystal of an anti-idiotypic antibody is a distinct invention, NOT a species. Applicant is also required to list ALL claims which would read on the elected crystal of an anti-idiotypic antibody as described in the preceding example of Embodiment I**)

III. Claims 4-11, 14-39, 43-68, 70-71, and 74-76, as specifically drawn to a crystal of an antibody, a composition or formulation containing a crystal of the antibody, a large batch crystallization method and a diagnostic kit, classified in class 530, subclass 387.3; class 424, subclass 178.1.
(**Applicant must choose ONE specific crystal of an antibody as a group, as each crystal of an antibody is a distinct invention, NOT a species. Applicant is also required to list ALL claims which would read on the elected crystal of an antibody**)

An appropriate group selection of Embodiment III would be for example, Abciximab (claim 14) is the specific antibody which can be characterized as being monoclonal (claim 6), chimeric (claim 8), used therapeutically (claim 5) for the treatment of cardiovascular diseases (claim 16), which can be placed within the anti-GPIIb/IIIa receptor antibodies (claim 15).
(The applicant is not limited to the claims provided by the example described above and is required to list ALL claims which would read on the elected crystal of an antibody)

IV. Claims 40-42, and 77-78, as specifically drawn to a method of treating a mammal by administering a crystal of an antibody or a formulation or a composition, classified in class 424, subclass 130.1
(**Applicant must further choose ONE specific crystal of an antibody or specific composition or specific formulation, as each crystal of an antibody or composition or formulation is a distinct invention, NOT a species**)

V. Claim 69, as specifically drawn to a method of purifying a protein by affinity matrix purification, classified in class 424, subclass 130.1; class 530, subclass 413.

VI. Claims 72-73, as specifically drawn to an *in vitro* diagnostic method for detecting the presence of an antigen in a sample, classified in class 530, subclass 388.1, 389.1.

It is noted that the claims of the instant application have been determined to include linking claims. Claims 1-3 will be examined along with whichever group the applicant elects for Embodiments I-III. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claims 1-3. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

The inventions are distinct, each from the other because of the following reasons:

The inventions of the various groups within Embodiments I-III, as disclosed, are biologically and chemically distinct products, unrelated in structure and function, made by and used in different methods, and are therefore distinct inventions.

The invention of the various groups within Embodiments IV-VI are materially distinct methods which differ at least in objectives, method steps, reagents and/or dosages and/or schedules used, response variables, and criteria for success

The inventions of Embodiments I-III and the method of Embodiment IV are related as products and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the method of administering a crystal of an antibody for the treatment of a mammal can be practiced with a materially different product such as those listed in Embodiments I-III.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper. Furthermore, because these inventions are distinct for the reasons given above and the search of the literature required for one group is not required for another group, restriction for examination purposes as indicated is proper.

Species Election

Claims 34-37 of Embodiments I, III are generic to a plurality of disclosed patentably distinct species comprising distinct polymeric carrier such as:

Biodegradable, biocompatible, poly (cyanoacrylates), poly (depsipeptide), ect..

Claim 39 of Embodiments I, III is generic to a plurality of disclosed patentably distinct species comprising distinct stabilizers such as:

Sucrose, trehalos, lactitol, gelatin, ect..

The products of the above species represent separate and distinct molecules with different structures and functions such that one species could not be interchanged with the other. As such, each species would require different searches and consideration of different patentability issues.

Additionally, the steps and reagents of the above species are completely distinct and impart different biological functions and use such that one species could not be interchanged with the

other. As such, each species would require different searches and the consideration of different patentability issues.

Applicant is required under 35 U.S.C 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant transverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior are, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Note:

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

> In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brandon J Fetterolf, PhD whose telephone number is (571)-272-2919. The examiner can normally be reached Monday through Friday from 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571)-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Brandon J Fetterolf, PhD
Examiner
Art Unit 1642

BF

Christina Chan

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